K020746

APR 2 2 2002

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

| | |
|---|---|
| Manufacturing Site: | Bird Products Corporation<br>1100 Bird Center Drive<br>Palm Springs, CA 92262 |
| Contact: | Tom Gutierrez (760) 778-7255 (phone); (760) 778-7274 (fax) |
| Summary Date | August 11, 2000 |
| Device Trade Name: | TBird VELA Ventilator |
| Device Common/Classification Name: | Classification name: 868.5895 Continuous Ventilator, 73 CBK |
| Establishment Registration Number | 2021710 |
| Device Class: | Class II |
| Classification Panel: | Anesthesiology |
| Predicate Device: | The predicate devices are: |

| | | |
|---|---|---|
| 1 K950484 | TBIRD AVS | Bird Products Corporation |
| 2 K920113 | Bird Graphics Monitor | Bird Products Corporation |
| 3 K973646 | Bird Sentry Blender | Bird Products Corporation |
| 4 K911336 | Bird Nebulizer Synchronizer | Bird Product Corporation |

Device Description:

The TBird VELA Ventilator employs a turbine gas delivery system along with microprocessor control to provide support for pediatric to adult patients. Capable of delivering clinically advanced modes of ventilation like Pressure Support with an internal battery or AC power the TBird VELA Ventilator has an extensive patient range.

The TBird VELA Ventilator ventilator pneumatic system is an electromechanical system comprised of four major subsystems, each containing several components. These systems include the flow delivery system, the exhalation system, the safety system and the inspiratory hold valve.

This electromechanical system controls all inspiratory flow to the patient. The exhalation system controls the flow of gas from the patient's lungs during the exhalation phase. The mechanical safety system ensures that the patient can breath spontaneously from room air and that the patient pressure is limited to a maximum value in the event of a ventilator malfunction. When activated, the inspiratory hold valve blocks flow between the flow delivery system and the patient.

The TBird VELA Ventilator ventilator electronic system is comprised of several subsystems, each containing numerous components. These subsystems include the Graphical User Interface System, the Power System, the Main Controller System, Exhalation, and Flow Delivery systems. The Display System is comprised of three Alarm Setpoint Displays, seven Control Setpoint Displays, up to forty-eight Message Display characters, up to twenty-five Discrete Indicators, and a bargraph style Manometer. The Main Controller System is comprised of three Pressure Transducers, an Analog-to-Digital Converter, two Digital-to-Analog Converters, the Input-Output Processor, Solenoid Valves, and the Watchdog and Hardware Fault Monitors. The Power System conditions and controls energy from the AC line input, the internal battery, and the optional external battery pack. When energy is available from the AC line, the ventilator operates from this source, as well as recharging the internal battery.

Intended Use:

The TBird VELA Ventilator is intended to provide continuous or intermittent mechanical ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lbs.), who require the following general types of ventilatory support, as prescribed by an attending physician:

- Positive pressure ventilation
- Assist/Control, SIMV, CPAP modes of ventilation

The ventilator is suitable for use in institutional and transport settings. It is not intended for use as an emergency medical transport ventilator

Substantial Equivalence

The TBird VELA Ventilator is the same device as the TBird AVS Ventilator, which was cleared for market under 510(k) K950484. The name of the device was changed to the TBird VELA.

Modifications to the TBird VELA Ventilator are associated with this submittal

- Graphical User Interface (GUI) touch-screen/display
- OXYGEN monitor
- Nebulizer high pressure gas source.
- Exhalation flow sensor was also modified to incorporate a direct hard wire connection

The modified TBird VELA Ventilator have the following similarities to those which previously received 510(k) concurrence:

- have the same indicated use,
- use the same ventilation operating principle,
- incorporate the same basic ventilator design with the exception of modifications described in this submittal.
- incorporate the same basic electronic control system with the exception of modifications described within this submittal.
- are manufactured and packaged utilizing the same basic processes.

- In summary, the TBird VELA Ventilator described in this submission is, in our opinion, substantially equivalent to the predicate device(s).

Summary of Testing and Validation:

Performance testing verified that the TBird VELA Ventilator meets it's performance requirements and that this device is substantially equivalent to medical devices currently legally marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2002

Mr. Tom Gutierrez
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262

Re: K020746
TBird VELA Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II (two)
Product Code: 73 CBK
Dated: February 29, 2002
Received: April 1, 2002

Dear Mr. Guitierrez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indication For Use

510 (k) Number (if known): K020746 Page 1 of 1

Device Name: TBird VELA Ventilator

Indication For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020746

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 cfr 801.109)

(Optional Format 1-2-96)